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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,983	03/19/2007	Nareak Douk	PA1759	3746
28390 7590 11/12/2008 MEDTRONIC VASCULAR, INC. IP LEGAL DEPARTMENT 3576 UNOCAL PLACE SANTA ROSA, CA 95403				
EXAMINER WOLF, MEGAN YARNALL				
ART UNIT		PAPER NUMBER		
3738				
NOTIFICATION DATE		DELIVERY MODE		
11/12/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

Office Action Summary

Application No.

10/560,983

Applicant(s)

DOUK ET AL.

Examiner

MEGAN WOLF

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☒ Claim(s) 1 and 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 7/11/08 have been fully considered. Arguments regarding the rejection of claims 13-16 under 35 U.S.C. 102(b) as being anticipated by Houser are persuasive and the rejection is withdrawn. However, arguments regarding the rejection of claims 1-4 and 7 as being anticipated by Houser are not persuasive. While Houser illustrates use of the device with one chordae tendinae in fig.22B, the device shown in figs.21A and 21B is capable of being used to surround a plurality of chordae tendinae as claimed. Applicant's arguments and amendments to claims 1 and 4 are directed to the intended use of the device of which Houser is capable of. Structurally the device of Houser shown in figs. 21A and 21B is anticipated by the claim. The device of Houser is even directed to shortening of the chordae tendinae as the present claims require. Finally, if one were to use the device of Houser, which comprises a filamentous body of shape memory material and transitions between a linear delivery configuration to an annular treatment configuration (figs.21A,B), to surround and contact a plurality of chordae tendinae, the plurality of chordae tendinae would be drawn closer together to form a bundle of effectively shortened chordae tendinae.
2. Applicant's arguments with respect to the rejection of claims 4-12 in view of Langberg have been considered but are moot in view of the new ground(s) of rejection.

Claim Objections

3. Claims 1 and 4 are objected to because of the following informalities: in claims 1 and 4, "chordate" is believed to be in error for --chordae--. "Chordate" is not found in the

specification and is not known for use in describing chordae. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 contains trademarks to identify a particular material, which renders the claim indefinite. See MPEP 2173.05(u) paragraph 2.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-4 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Houser et al. 2002/0035361 (submitted in IDS). Houser discloses a girdle for surrounding a plurality of chordae tendinae (CT) comprising filamentous body 306 comprising a shape memory material (par.111) to allow transition between a linear delivery configuration (21A) and an annular treatment configuration (fig.21B), wherein

the annular treatment configuration is capable of contacting a plurality of CT and drawing the plurality of CT closer together to form a bundle of effectively shortened CT.

8. Re claims 2 and 3, see par. 111 and fig. 22B.

9. Re claims 4 and 7, Houser discloses a system for treating a heart valve comprising elongate delivery catheter 302 having a lumen, and shape memory girdle 306 having an annular treatment configuration 21B sized and shaped to be capable of surrounding a plurality of CT and to draw the plurality of CT closer together to form a bundle of effectively shortened CT, girdle 306 having a linear delivery configuration (fig.21A) sized and shaped to be releasably disposed within the lumen of delivery catheter 302 (figs. 22A & B; pars. 111-112).

10. Claims 1-7, and 13-16 are rejected under 35 U.S.C. 102(e) as being anticipated by St. Goar et al. 6,629,534 (submitted in IDS).

11. Re claims 1-3, St. Goar discloses girdle 103 comprising a filamentous body of shape memory material such as nitinol to allow transition between a linear delivery configuration and an annular treatment configuration, wherein in the annular treatment configuration body 103 contacts a plurality of CT, drawing the plurality of CT closer together to form a bundle of effectively shortened CT (col.27, ll.47-67; figs.39,40).

12. Re claims 4-7, St. Goar discloses the girdle as described above as well as a catheter 120 having lumen 124, wherein the catheter contains a push rod slidably disposed within the lumen of the delivery catheter for pushing the girdle out of the delivery catheter (col.28, ll.1-8). The push rod is inherently flexible, including at a distal portion, so that it may traverse the vasculature of the patient.

13. Re claims 13-16, St. Goar discloses a method for treating a heart valve comprising percutaneously delivering girdle 130 in lumen 124 of catheter 120 adjacent the heart valve by positioning the catheter proximate a plurality of CT of the heart valve, releasing the girdle, and encircling the plurality of CT of the heart valve with the girdle, wherein the catheter is advanced transluminally to a left ventricle through an aortic valve (fig.40; col.27, l.47-col.28, l.8).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 8, 9, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Houser et al. 2002/0035361 (Houser '361) or St. Goar et al. 6,629,534 in view of Houser et al. 2002/0173808 (Houser '808). Both Houser '361 and St. Goar disclose the invention substantially as claimed and as discussed above including that the girdle comprises an elongate body having first and second ends. However, neither Houser '361 nor St. Goar disclose a locking mechanism for locking the girdle in an annular treatment configuration, wherein the locking mechanism comprises hooks on the ends of the elongate body or a lumen lock portion and tooth on the ends of the elongate body.

Houser '808 teaches several embodiments of locking mechanisms for retaining rings, in the same field of endeavor, wherein the locking mechanism may comprise

engaging hooks 128 at the ends of the elongate body (fig.11h; par.110), or a lock portion having a lumen for receiving the second end and teeth at the second end for engagement with the lock portion (fig.11e; par.107), both locking mechanisms intended for the purpose of securing the ring in the closed position (pars.107,110).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the ends of the annular girdles disclosed by either Houser '361 or St. Goar to include any of the locking mechanisms taught by Houser '808 in order to more firmly secure the girdle in the annular treatment configuration.

16. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al. 2002/0035361 (Houser '361) or St. Goar et al. 6,629,534 in view of Houser et al. 2002/0173808 (Houser '808) as applied to claim 8 above, and further in view of Phillips 2003/0033006. Houser '361 or St. Goar in view of Houser '808 discloses the invention substantially as claimed. However, Houser '361 or St. Goar in view of Houser '808 does not disclose an elongate tether releasably attached to the girdle. Phillips teaches a securing ring, in the same field of endeavor, comprising a releasable tether 70 attached to the catheter-delivered ring for the purpose of adjusting the position of the device (pars.35,36). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the girdle of Houser '361 or St. Goar in view of Houser '808 to include a tether releasably attached thereto as taught by Phillips in order to correct and adjust the position of the device during implantation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MEGAN WOLF whose telephone number is (571)270-3071. The examiner can normally be reached on Monday-Friday 7:00-4:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. W./
Examiner, Art Unit 3738
10/29/08

/Bruce E Snow/
Primary Examiner, Art Unit 3738